

REMARKS/ARGUMENTS

The Examiner's attention to the present application is noted with appreciation.

Amendment of Claims. Claim 1 is amended to incorporate the limitation of claim 3, and claim 3 is canceled. The Office Action indicates (paragraph numbered 9, page 17) that claims 3-6, 10, 21 and 25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten. This is done with respect to claim 3, and it is asserted that claims 1 to 10 are thereby allowable. With respect to claims 21 and 25, it is asserted that the base claims are allowable, as hereafter argued, and such claims are accordingly not amended.

Claim 29 is amended, to include the limitation that the first and second biosensors are screen-printed, thick-film biosensors. New claim 49 is added, dependent on claim 29, and relating to a dual sensor test strip. Support for the amendment and new claim 49 is found at page 11, lines 16-25, and elsewhere. Because claim 3 is canceled, no additional claim fee is believed to be due. If any additional fee is deemed due on account of new claim 49 or otherwise, authorization is given to charge payment of any additional fees required to Deposit Acct. 13-4213.

Rejection of claims 1 and 7 under 35 U.S.C. § 103(a) as being unpatentable over Ikariyama et al. and Yamaguchi. (Office Action paragraph numbered 4, page 3) Claims 1 and 7 are asserted to be unpatentable over the cited references. However, in paragraph numbered 10 of the Office Action, page 17, claim 3 is indicated as being allowable in that there is no suggestion to substitute rhodium, iridium or ruthenium, as provided in claim 3. The limitation of claim 3 has been incorporated into claim 1 by amendment, and is asserted that claim 1 is accordingly allowable. Claim 3 is canceled. Given that claim 1 is allowable, it is asserted that dependent claims thereto (claims 2 and 4-10) are similarly allowable.

Rejection of claims 11-20, 22-24, 26-28, and 34-48 under 35 U.S.C. § 103(a) as being unpatentable over Ikariyama et al. in view of Yazaki and Zwaodzinski. (Office Action paragraph numbered 5, page 4) Claims 11-20, 22-24, 26-28, and 34-48 are asserted to be unpatentable over the cited references. This rejection is respectfully traversed. With respect to claim 11, the limitations include a

sleeve with a length of at least about 0.2 mm, with the cavity within the sleeve containing the composite, and the ratio of the surface area of the composite to the volume of the composite being at least about 1:8. The Office Action (page 5) states that Ikariyama does not disclose either the 0.2 mm length limitation or the 1:8 surface area to volume limitation. It is asserted (Office Action page 6) that the length is a matter of scaling and that the surface area to volume is a matter of scaling or optimization. Applicant asserts that the specification discloses that unexpected results are obtained with these specified parameters. See, e.g., Specification at page 12, line 21, bridging page 13, line 14. The Zawadzinski reference (U.S. 5,227,042) specifically discloses only a "coating **14**" that preferably contains a "perfluorosulfonic acid polymer." See col. 3, line 58 to col. 4, line 3. While it is disclosed the polymers "act as solute for oxygen to provide an oxygen source for the enzyme reaction" (Id.), the "coating" serves only to stabilize oxygen levels. This may be seen from Fig. 5 of Zawadzinski and the accompanying text (col. 6, lines 6 to 31). It is specifically stated that the glucose was detected (and incrementally added) in a "solution having dissolved oxygen and oxygen is also supplied to the perfluorosulfonate acid polymer material by opening the backside of the carbon paper electrode to air." (See col. 6, lines 9-12) This is shown in Fig. 5 by the point up to the first arrow indicating "argon into electrode." When argon is introduced into the back of the electrode, the sensor immediately stops detecting glucose. When oxygen is introduced into the electrode (as shown by the first arrow indicating "oxygen into electrode", the electrode again detects glucose. This is then repeated with the same results. This graph and the accompanying text thus establish that because Zawadzinski et al. discloses only a "composite coating" (from abstract), there is not sufficient oxygen-binding capability to support catalytic detection of glucose absent either dissolved oxygen in solution or oxygen "introduced through the electrode structure **12** to enzyme layer **14**." (Col. 5, lines 65-66) By contrast, Applicant's invention specifically provides for "measurements in an oxygen-depleted environment." (See Specification at 12, lines 24-28) Additionally, Applicant specifically distinguishes his invention from that of Zawadzinski et al. (See, e.g., Specification at page 13, lines 6-9: "However, the method of this invention must be distinguished from applications wherein a coating or thin layer is

provided which, even if including a fluorocarbon, would contain only sufficient oxygen to support an oxygen-dependent enzymatic reaction, in the absence of endogenous oxygen, for a few seconds or at most, a few minutes.”)

Nor does the Yazaki reference provide anything other than a “thin layer” electrode. The abstract specifically states that the porous electrode has a “0.5 mm thickness” and the electrode is “equipped to the end of a glass tube of 4 mm outer dia.” Thus the ratio is clearly not on the order of 1:8 as taught by Applicant. Further, that the Yazaki device might make a measurement at a lower oxygen concentration is consistent with Applicant’s disclosure that a “thin layer” will provide sufficient oxygen to function for “a few minutes.” However, this does not anticipate or make obvious a device, as taught and claimed by Applicant, that can be employed for “over 40 hours of actual operation.” (Specification at 13, lines 3-4)

It may thus be seen that the 1:8 ratio of surface area to volume provides an entirely new and unexpected functionality, oxygen-dependent enzyme detection in an oxygen depleted environment without an external supply of oxygen. Zawodzinski teaches only optimizing ratios in a device which is limited to either use in a solution having dissolved oxygen or in a device with an external supply of oxygen. Yazaki teaches only a thin layer electrode. Applicant teaches, and has discovered, that by minimizing the surface area of the electrode (Applicant teaches that oxygen consumption depends on surface area, Specification at 12, lines 10-11), and providing a large volume of oxygen-rich binder, the device may be employed in oxygen-depleted environments. Given that Zawadzinski does not teach or suggest that his device may be used in oxygen-depleted environments unless an external oxygen source is provided, no amount of “scaling” or “optimization” would result in Applicant’s invention. Accordingly, the combination of Ikariyama in view of Yazaki and Zawodzinski does not render claim 11 unpatentable. Claim 11 being allowable, it follows that dependent claims 12-20, 22-24 and 26-28 are also allowable.

Claim 34 similarly contains the limitation that the composite have a ratio of surface area of the electrode end to volume of the composite of at least about 1:8, and further provides that the biosensor is employed “in the absence of exogenous oxygen.” For the reasons given above, the combination of

Ikariyama in view of Yazaki and Zawodzinski does not render claim 34 unpatentable. Claims 35 to 48 are dependent claims, and are similarly allowable.

Rejection of claim 2 under 35 U.S.C. § 103(a) as being unpatentable over Ikariyama et al. in view of Yamaguchi at applied to claim 1 and further in view of Yazaki, El Murr or Zawodzinski. (Office Action paragraph numbered 6, page 13) Based on the amendment to claim 1 and the argument with respect to claim 1 presented above, it is asserted that claim 1 is patentable. Accordingly, claim 2, which depends on claim 1, is patentable.

Rejection of claims 8 and 9 under 35 U.S.C. § 103(a) as being unpatentable over Ikariyama et al. in view of Yamaguchi at applied to claim 1 and further in view of Yazaki or Zawodzinski. (Office Action paragraph numbered 7, page 14) Based on the amendment to claim 1 and the argument with respect to claim 1 presented above, it is asserted that claim 1 is patentable. Accordingly claims 8 and 9, which depend on claim 1, are patentable.

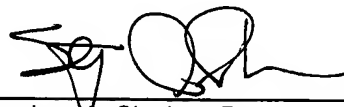
Rejection of claims 29-33 under 35 U.S.C. § 103(a) as being unpatentable over the Derwent abstract of Yazaki in view of Gorski et al. and Wong et al. or Ward et al. (Office Action paragraph numbered 8, page 15.) The rejection is respectfully traversed. As amended, claim 29 is drawn to screen-printed, thick-film biosensors. None of the cited references disclose a screen-printed, thick-film biosensor. Yazaki discloses a complex manufacturing process including heating to 300-400° C under a pressure of 100-300 kg/cm². Gorski discloses a conventional ruthenium-oxide-type catalytic film on a carbon fiber microelectrode (see Abstract). Wong discloses a conventional "noble metal (e.g., platinum or gold) working electrode" (col. 2, ll. 32-33) with a hydrophilic membrane (col. 2, ll. 50-53). Ward discloses a "platinum anode" (col. 4, ll. 43-62) with an enzyme layer and semipermeable membrane. Thus none of the prior art references suggest or teach simultaneous detection utilizing screen-printed, thick-film biosensors. New claim 49, which depends from claim 29, further provides that the first and second biosensors are disposed on a dual sensor test strip.

Conclusion. In view of the above amendments and remarks, it is respectfully submitted that all grounds of rejection and objection have been avoided and/or traversed. It is believed that the case is now in condition for allowance and same is respectfully requested.

If any issues remain, or if the Examiner believes that prosecution of this application might be expedited by discussion of the issues, the Examiner is cordially invited to telephone the undersigned attorney for Applicant at the telephone number listed below.

Respectfully submitted,

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